UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **WAVE TWO PROLIFT, PROLIFT+M AND PROSIMA CASES LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF RUSSELL DUNN, PH.D., P.E.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this reply memorandum in support of their motion [Dkt. 2385] to exclude the opinions and testimony of Russell Dunn, Ph.D., P.E., Plaintiffs' chemical engineering expert.

I. ARGUMENT

A. Dr. Dunn Is Unqualified to Offer His Opinions; This Court Has Repeatedly Held So; and the *Huskey* Decision Says Nothing About Dr. Dunn's Lack of Qualifications

Plaintiffs' Response [Dkt. 2540] says nothing about the fact that this Court has found Dr. Dunn unqualified to offer his proffered opinions in more than two dozen vaginal mesh cases. Similarly, Plaintiffs make no argument as to why Dr. Dunn is now suddenly qualified to offer his opinions. Ignoring this Court's precedent does not cure the inadmissibility of Dr. Dunn's opinions. The Court should do as it has done so many times before and find Dr. Dunn's testimony inadmissible.

Instead of addressing the Court's prior holdings finding Dr. Dunn unqualified to offer his opinions, Plaintiffs make much ado over the fact that this Court denied Ethicon's *Daubert*

challenge to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014). As this Court has expressly and repeatedly noted, Ethicon's *Daubert* challenge in *Huskey* did not challenge Dr. Dunn's qualifications. *See Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047, at *65-66 (S.D. W. Va. May 6, 2015) ("[T]he plaintiffs first note that this court rejected certain *Daubert* objections to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-11 (S.D. W. Va. 2014). However, Ethicon did not object to Dr. Dunn's qualifications in *Huskey*, as BSC has done here."). The Court then found, on the same facts before it here, that "Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case…." *Id.* at *68-69.

Ethicon's motion to exclude Dr. Dunn in *Huskey* was filed relatively early in this litigation. Much has been learned about Dr. Dunn and his lack of qualifications since that decision. In the related Boston Scientific litigation, the Court has repeatedly found that Dr. Dunn's education, training, and experience does not qualify him to offer opinion testimony in vaginal mesh litigation.

Plaintiffs also repeatedly argue in their Response that the Court has never excluded Dr. Dunn from testifying "in any Ethicon case." *See, e.g.*, Pls.' Resp. [Dkt. 2540] at 3. To be sure, there are only two cases in which the Court has reached the merits of a motion to exclude the opinions of Dr. Dunn in an Ethicon case – *Huskey* and *Edwards*. *Edwards*, like *Huskey* was early in this litigation and did not involve a qualifications challenge. Simply put, the Court has not had the occasion to address Dr. Dunn's lack of qualifications "in any Ethicon case."

More importantly though, Dr. Dunn's qualifications do not change based on the manufacturer of the product at issue. If Dr. Dunn lacks the qualifications to opine about the

Boston Scientific vaginal mesh, he necessarily lacks the qualifications to opine about Ethicon's vaginal mesh.

Nothing has changed regarding Dr. Dunn's lack of qualifications, and the Court should affirm its numerous prior holdings by yet again excluding Dr. Dunn to his lack of qualifications. *See, e.g., Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 (S.D. W. Va. May 6, 2015).

B. Plaintiffs' Response identifies nothing that would qualify Dr. Dunn to opine regarding risk management/quality systems process for medical devices

Not only have Plaintiffs failed to distinguish this Court's prior holdings regarding Dr. Dunn's lack of qualifications, Plaintiffs direct the Court to nothing, other than Dr. Dunn's self-serving statements, to support their argument that he is qualified to offer risk management or quality systems process opinions in a medical device case. The only things to which Plaintiffs cite for the proposition that Dr. Dunn is qualified to offer medical device opinions are Dr. Dunn's report and his deposition. *See* Pls.' Resp. [Dkt. 2540] at 6, n.10 & 11. In both, Dr. Dunn declares himself qualified to opine in a field for which no one – other than Plaintiffs – have ever hired him to operate.

In their Response, Plaintiffs do not contest the fact that Dr. Dunn is a veritable stranger to medical devices. He has never performed any type of risk analysis for medical devices, never taught on the subject, never published on the subject, never designed a product, and never been consulted in the design of a product. Dunn 11/20/15 Dep. Tr. [Dkt. 2385-3] 241:23-252:10. Plaintiffs say nothing about this lack of experience.

Instead, they contend that identifying the risks for a human implant is the same as identifying risks in a spacecraft. Pls.' Br. [Dkt. 2540] at 6 (claiming the FMEA process "remains the same whether it is used by NASA for the space shuttle or if it is used in the products at

issue"). In support of this argument that outer space and the human body require the same risk assessment, Plaintiffs cite to nothing other than the *ipse dixit* of Dr. Dunn's Report, wherein he attempts to connect his experience in the aerospace and automotive industry to the female anatomy. *See id.* (citing Dunn Report [Dkt. 2385-2] at 23).

C. Dr. Dunn's lack of credentials is further demonstrated by his total unawareness of the standards applicable to medical devices

Plaintiffs' Response makes readily apparent that Dr. Dunn lacks the qualifications to offer his risk management and quality systems process opinions within the context of medical devices. Plaintiffs admit that device manufacturers generally (and Ethicon specifically) are not required to use the FMEA process for its risk management and quality systems process. Rather, manufacturers are free to select from any number of risk management/quality systems processes. *See* Pls.' Resp. [Dkt. 2540] at 6-8. But then Dr. Dunn insists that if a medical device manufacturer chooses to employ an FMEA as its process, then the FMEA "must contain every failure mode considered." Pls.' Resp. [Dkt. 2540] at 9.

Plaintiffs contend that Dr. Dunn can opine about the application of an FMEA in the medical device context because an FMEA is the same, whether the product is vaginal mesh or spaceships. The problem, as explained in Ethicon's Memorandum, is that ISO 14971 – a standard designed specifically for medical devices – expressly provides that when prior analyses of a potential risk, such as oxidation, are available for a component of a medical device, the manufacturer need not repeat the analysis of that risk, but rather "can and should" rely on the prior analysis. ISO 14971:2007 [Dkt. 2385-8] at 19. Moreover, ISO 14971 expressly provides that risk analysis of degradation be conducted in accordance with ISO 10993. *Id*. at 76-77. Dr. Dunn simply ignores these important standards.

Plaintiffs' Response confirms Dr. Dunn's position that there is no need for him to rely on the ISO standards to form his opinions because "the FMEA is a recommended mode of risk assessment for medical devices by those same ISO standards—and everything suggested in those guidelines is part of the FMEA." Pls.' Resp. [Dkt. 2540] at 7. Plaintiffs failed to give, and indeed could not give, any citation in ISO 14971 or any other standard to support this incorrect proposition.

Dr. Dunn's insistence that the term "oxidation" must expressly be listed and analyzed within a separate FMEA for each product is a demonstration of his lack of qualification to offer opinions in the context of medical devices. Pls.' Resp. [Dkt. 2540] at 8. This position glaringly reveals Dr. Dunn's lack of expertise in FMEAs for medical devices under ISO 14971. Instead of following ISO 14971, Plaintiffs candidly acknowledge that Dr. Dunn is not applying the ISO standard for medical devices and admit that Dr. Dunn's position is that the FMEA "must contain every failure mode considered." Pls.' Resp. [Dkt. 2540] at 9. It may be that when it comes to spaceships the FMEA "must contain every failure mode considered," but when it comes to medical devices, the industry standards are clear: Not only are manufacturers permitted to incorporate prior risk analysis, manufacturers are expressly encouraged to do so. ISO 14971:2007 [Dkt. 2385-8] at 19.

Having blinded himself to all analyses that are not repeated every time a new FMEA is created, Dr. Dunn arrives at the untenable position that Prolene has not been evaluated for oxidation. Pls.' Resp. [Dkt. 2540] at 7. Dr. Dunn could not arrive at this opinion if he had considered the various biocompatibility risk assessments performed on the Prolene mesh pursuant to ISO 10993, as discussed in Ethicon's Memorandum. Because he applied the wrong

methodology – a methodology he is not qualified to perform – Dr. Dunn's opinions are unreliable and inadmissible.

D. Dr. Dunn's lack of experience with ISO 10993 renders him unqualified

Plaintiffs say that Dr. Dunn's lack of familiarity with ISO 10993 is irrelevant because the "FMEA comports with every standard for medical device risk analysis that is described in the ISO standards—which includes the need for any biocompatibility testing or analysis described in ISO 10993." Pls.' Resp. [Dkt. 2540] at 10. That is not a true statement. Dr. Dunn opines that Ethicon's risk analysis of Prolene should have included more testing for oxidative degradation. He had no idea that ISO 10993 includes the standard for determining whether more testing is needed. Dr. Dunn cannot possibly be considered an expert to opine that Ethicon should have conducted further testing of Prolene for oxidative degradation when he does not even know there is a formal standard that governs the determination as to whether additional testing is needed.

E. Plaintiffs' efforts to circumvent Dr. Dunn's lack of credentials render Dr. Dunn's opinions irrelevant

In an attempt to rehabilitate Dr. Dunn from a credentials standpoint, Plaintiffs essentially argue that his opinions will be unhelpful in this case. First, Plaintiffs disavow any and all efforts by Dr. Dunn to opine that Prolene degrades *in vivo*. Dr. Dunn has not studied this issue and has no qualifications in the area of biocompatibility. *See* Pls.' Resp. [Dkt. 2540] at 1, 11.

In recognition of Dr. Dunn's lack of qualifications to opine as to whether Prolene degrades *in vivo*, Plaintiffs' Response abandons the central theme of Dr. Dunn's Report –*in vivo* degradation of Prolene. *See* Pls.' Resp. [Dkt. 2540] at 1, 11. Plaintiffs' abandonment of Dr. Dunn's opinion that Prolene degrades *in vivo* renders his entire report irrelevant. If Dr. Dunn is going to testify (as Plaintiffs now suggest) that he does not know if Prolene degrades *in vivo*, that he has done nothing to determine if Prolene degrades in *vivo*, and that, even if it does degrade *in*

vivo, he has no opinion as to whether such degradation can cause a clinical harm, then Dr. Dunn's opinions are wholly unhelpful to the jury.

F. Dr. Dunn's "Polymer Failure Opinions" are challenged

Plaintiffs say that Ethicon has not challenged Dr. Dunn's "Polymer Failure Opinions." Pls.' Resp. [Dkt. 2540] at 1. That is not true. Ethicon's Motion to Exclude Dr. Dunn based on his lack of qualifications goes to the entirety of his report.

To the extent that Plaintiffs are attempting to argue that Ethicon did not challenge Dr. Dunn's "Polymer Failure Opinions" on any grounds other than qualifications, Plaintiffs are blurring the distinction between "Polymer" in general and Prolene. Ethicon's Memorandum specifically challenges all of Dr. Dunn's Prolene failure opinions. But a large portion of the "Polymer Failure Opinions" section in Dr. Dunn's report concerns unstabilized (or generic) polypropylene, not Prolene. It is true that Ethicon does not challenge Dr. Dunn's opinion that unstabilized polypropylene can degrade. Ethicon's Memorandum explained that its objection to this opinion is simply that it is not relevant, is not helpful to the jury, and in fact would tend to confuse the jury given that there is a very significant difference between unstabilized polypropylene and Prolene. *See* Mem. [Dkt. 23] at 17-18, 19-20.

II. CONCLUSION

For the reasons set forth above, the Court should exclude the opinions and testimony of Dr. Dunn.

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on August 18, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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